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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,037	10/27/2003	Cynthia T. Clague	P-11210.00	3891

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MEDTRONIC, INC.
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EXAMINER

KOTINI, PAVITRA

ART UNIT	PAPER NUMBER
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3731

MAIL DATE	DELIVERY MODE
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06/05/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/694,037

Applicant(s)

CLAGUE ET AL.

Examiner

Pavitra Kotini

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) 7-14, 24-31 and 35-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 15-24 and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 12/6/04, 2/24/04.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, Species 3 in the reply filed on 4/30/07 is acknowledged. The traversal is on the ground(s) that there is no significant change in the burden to examine all three species. This is not found persuasive because as delineated in the instant specification, the first embodiment (figs. 13-16) have various features such a plunger, push-button, a retention cap. The second embodiment (figs. 17 and 18) include yet another variation of a flexible remote control. Lastly, the elected species (figs. 19-24) are drawn to pistol type handgrip. Hence, there are distinct species disclosed in the invention that would place undue burden on the examiner to search for these different structural variations. The requirement is still deemed proper and is therefore made FINAL.

Regarding the generic claims, the Applicant's arguments are persuasive and the Examiner concurs that claims 1 and 18 are generic claims.

Claims 7-14, 24-31, and 35-46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Shapiro (US-5314440).

Shapiro discloses a vessel wall cutting instrument for making an elongated slit through a vessel wall of a body vessel of a patient having a vessel axis from an exterior surface to an interior surface of the vessel wall into a lumen of the body vessel comprising:

Regarding **claims 1 and 18**, an elongated instrument shaft (12) extending between a shaft proximal end and a shaft distal end (fig. 1) and having an instrument shaft axis (longitudinal axis) the elongated instrument shaft comprising a fixed or first shaft member (60) and a movable or second shaft member (62) adapted to move with respect to the fixed shaft member in the direction of the instrument shaft axis (col.4, lines 8-38); a first or fixed cutting blade (70) fixed to the first or fixed shaft member (60) at the shaft distal end to extend substantially laterally to the instrument shaft axis to a first or fixed cutting blade free end, the first or fixed cutting blade (70) having a blunt distal leading blade side (rounded distal side of 70), a proximal, trailing side having a first or fixed cutting edge (72), and a cutting tip (sharp pointed tip of 72) at the fixed cutting blade free end; a second or movable cutting blade (74) having a distal, leading edge (76) fixed to the second or movable shaft member (62) at the shaft distal end (68), the second or movable cutting blade extending substantially laterally to the shaft axis and having a second or movable cutting edge along the second or movable cutting

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blade distal, leading edge (fig.2); means for maintaining the second or movable shaft member in a retracted position with the second or movable cutting blade spaced proximally from the first or fixed cutting member (fig. 2); and means (20) for moving the movable shaft member with respect to the fixed shaft member (60) between the retracted position separating the fixed and movable cutting edges (fig.2) and an extended position wherein the first and second or fixed and movable cutting edges are substantially in side-by-side alignment to shear the vessel wall and form a slit therein (fig.3).

The statement of intended use: "as the blunt distal leading blade side is applied against the exterior surface of the vessel wall to depress the vessel wall and is moved laterally to pass the cutting tip of the fixed cutting blade through the vessel wall and into the lumen of the body vessel" has been carefully considered but deemed not to impose an structural limitations on the apparatus claims. The device of Shapiro is capable of being used as claimed if one desired to do so.

Regarding **claims 2 and 19**, the first or fixed cutting blade (70) is disposed to extend laterally to the shaft axis by a shank (66) having a shank proximal end mounted to the first or fixed shaft member (60) at the shaft distal end and extending distally substantially in parallel with the instrument shaft axis and alongside the movable cutting blade to a shank distal end (fig. 2); and the first or fixed cutting blade (70) extends laterally to the shaft axis from the shank (66) distal end to the fixed cutting blade free end and has a substantially straight fixed cutting edge (fig. 2).

The statement of intended use: "whereby the cutting tip at the fixed cutting blade free end is disposed against a body vessel wall substantially in alignment with the vessel axis as the blunt distal leading blade side is applied against the exterior surface of the vessel wall to depress the vessel wall and is moved laterally to pass the cutting tip of the fixed cutting blade through the vessel wall and into the lumen of the body vessel" is capable of being performed by the device of Shapiro and once again not given any weight in the absence of any structural limitations.

Regarding **claims 3 and 20**, the means for maintaining the first and second shaft members in a retracted position (fig. 2) comprises a spring (48) mounted between the first and second or fixed and movable shaft member and exerting retraction force there between (col.3, lines 22-25); and the moving means comprises means for transmitting force overcoming the retraction force to the second or movable shaft member to move the movable shaft member with respect to the first or fixed shaft member between the retracted position and the extended position (figs. 2 & 3; col.4, lines 23-45).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4-6, 15-17, 21-23, and 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shapiro (US-5314440) in view of Taylor et al. (US-6036641).

Shapiro discloses the invention substantially as claimed above, but fails to disclose stabilization means in combination with the vessel wall cutting instrument.

However, Taylor teaches various stabilization means including a means for suction (col.16, lines 18-21), an occlusion frame (figs. 10C and 36), and a means to apply compressive force (fig. 37A; col.29, lines 40-50). Therefore, it would have been obvious to a person of ordinary skill in the art, at the time of the invention to modify the vessel cutting device of Shapiro to include stabilization means as taught by Taylor. Such a modification would provide the advantage of allowing the physician to quickly and more safely finish the operation and the compression means would provide the advantage of varying the amount of occlusion of the blood vessels by varying the amount of compressive force (col.29, lines 50-53).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pavitra Kotini whose telephone number is 571-272-0624. The examiner can normally be reached on M-F 8:30am to 6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

P. Kotini

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(JACKIE) TAN-UYEN HO
PRIMARY EXAMINER
5/25/07